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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/849,686 08/21/97 DEGGERDAL

A 08269/003001

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HM22/0718

EXAMINER

OWENS JR. H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/849,686

Applicant(s)

Deggerdal et al.

Examiner

Howard Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 16, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Response to Arguments

5 The following is in response to the amendment filed 4/16/01:

An action on the merits of claims 1-26 is contained herein below.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 112(2) Rejection

15 The rejection of claims 5 and 24 under 35 U.S.C. 112(2) is withdrawn.

35 U.S.C. 102(e) Rejection

20 The rejection of claims 1-4, 9-11, 13, 16-18, 20, 22-24 rejected under 35 U.S.C. 102(e) as being anticipated by Cros et al., U.S. Patent No. 5,510,084 is withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

25 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Hawkins, U.S. Patent No. 5,898,071.

30 Claim 26 is drawn to a method of isolating nucleic acid from a sample comprising contacting said sample with a detergent and a solid support in the absence of any chaotropic agent, the solid support comprising an organic polymer wherein the sample is bound in a sequence independent manner in the presence of the detergent; subsequently separating the bound support from the sample.

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Hawkins teaches a method of isolating nucleic acid from a sample in the absence of any chaotropic agent via binding of the nucleic acid to a magnetic polymer bead in the presence of the detergent SDS (columns 4-9). Hawkins also teaches the subsequent separation of the sample from the bound support through wash steps with a buffer; as well as the packaging of this process in a kit (columns 8-9).

35 U.S.C. 103 Rejections

The rejection of claims 1-24 under 35 U.S.C. 103(a) as being unpatentable over newly cited Cros et al., U.S. Patent No. 5,510,084 and the 1994 Pharmacia Biotechnology Products Catalog is maintained for the reasons of record. Newly added claims 25 is also rejected under 35 U.S.C. 103(a) over Cros and Pharmacia.

With regards to the reference suggesting all of the limitations specifically the presence of a detergent and in the absence of a chaotropic agent, as cited previously "The Pharmacia Catalog discloses Oligo(dT) Cellulose which is an organic support which can bind nucleic acids in the presence of a detergent, buffers, salt, and chelating agents, then elute said nucleic acid upon heating". There is no evidence that one of skill in the art could not use the claimed Pharmacia invention in the absence of chaotropic agents. One of the facets of determining obviousness is not only determining the scope and contents of the prior art, but resolving the level of ordinary skill in the pertinent art. Applicant should note that the use of detergents such as SDS or Tween in nucleic acid separation is not novel since these agents are commonly used in cellular extraction buffers, which is a primary step prior to immobilization and routinely a part of the lysate solution that is not removed prior to immobilization.

As recited from the previous office action, the Pharmacia Catalog discloses oligo(dT) Cellulose (Product Code No. 27-5543-01) for the isolating of mRNA from a cell lysate which can certainly contain any conventional detergent. Oligo(dT) Cellulose is certainly an organic support which can bind mRNA in the presence of detergents. Furthermore, the material can be washed and the nucleic acid eluted with heat which

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simply denatures the double-stranded nucleic acid. One of skill in the art would clearly recognize that clearly recognize the common use of detergents within the art of purification of nucleic acids; moreover, that the Pharmacia product could be used in the absence of a chaotropic agent depending on the lysis buffer used when extracting the nucleic acids from the cells.

In support of the Pharmacia Product catalog, the Cros et al. reference is provided to show the obviousness of the use of solid supports and non-chaotropic buffers in the isolation or separation of nucleic acids. Cros et al. teaches the use of an organic polymeric support in the separation and isolation of nucleic acids of either DNA or RNA. Cros et al. teach the use of natural or synthetic materials which may or may not be chemically modified as solid supports such as nylon or polyacrylate. Cros et al. teach polymers such as polydivinylbenzene, polystyrene, polypropylenes, polyethylene and copolymers thereof as preferred supports for the immobilization of nucleic acids in diagnostic tests, affinity chromatography and in separation processes (col.4, line 17 - col.5, line 4); moreover, applicants claim language for the claims rejected under 35 U.S.C. 103 contain the broad claim language "comprising" and are silent with regard to direct binding as a limitation. Thus applicant's assertion that the Cros reference does not teach the invention as claimed because the binding is indirect, is not persuasive. Applicant's specification does not support the assertion that the claims are limited to direct binding as well and that the invention is inclusive of indirect binding. The specification on p.11 clearly states that the "[solid support may be modified to permit the selective capture of desired cells containing the nucleic acid. Thus for example, supports carrying antibodies, or other binding proteins]".

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

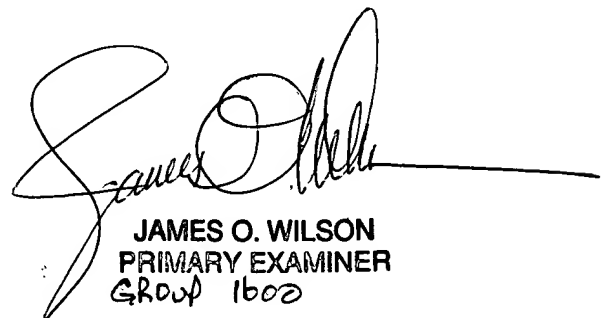
5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any
10 extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

20 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

25 Howard Owens
Group 1623



JAMES O. WILSON
PRIMARY EXAMINER
Group 1602